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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,234	04/06/2000	TSUTOMU AWAMURA	49668(281)	1287

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/529,234	Applicant(s) AWAMURA ET AL.	
	Examiner EVERETT WHITE	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2004 has been entered.
2. The amendment filed July 1, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 3, 4, and 7-9 have been canceled or previously canceled;
 - (B) Claims 1, 2, 5, 6, 10 and 11 have been amended;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (i) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.
3. Claims 1, 2, 5, 6, 10 and 11 are pending in the case.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 1, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, last line, reference to "sorbitol" as a monosaccharide or oligosaccharide renders the claim indefinite since "sorbitol" is not a monosaccharide or oligosaccharide.

In Claim 10, in the absence of the specific identity of the additional edible polymer of this invention, the identity of said additional edible polymer would be difficult to describe and the metes and bounds of said additional edible polymer that Applicants

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regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

In Claim 11, recitation of hydroxypropyl cellulose as the additional edible polymer is redundant since Claim 10, the independent Claim, already recites the presence of hydroxypropyl cellulose as an edible polymer. Hence, Claim 11 does not further limit the subject matter of Claim 10 and therefore, should be canceled.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Yamamura et al (US Patent No. 5,914,118).

Applicants claim a water soluble film preparation for oral administration comprising a drug, an edible polymer and a monosaccharide or an oligosaccharide, wherein the film is obtained by spreading and drying and has a drug elution rate of more than about 50% per 10 minutes and the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer in which the compound is

at least one of nilvadipine, phenytoin or griseofulvin, and the monosaccharide or oligosaccharide is sorbitol or reducing maltose starch syrup.

The Yamamura et al patent discloses a multi-layered film preparation for pain-killing and protecting an affected part of mucous membrane in the oral cavity, which comprises a water-soluble high molecular weight substance to be employed as a main base material. The Yamamura et al patent discloses that the main base material may be selected as hydroxypropylcellulose, hydroxypropylmethylcellulose and methylcellulose (for example), which anticipate the edible polymer of instant Claim 1. Yamamura et al discloses that the preparation may also include a drug and a plasticizer wherein the drug may be selected as griseofulvin (see column 3, line 66) and the plasticizer may be selected as sorbitol (see column 4, line 21). The limitation in Claim 1 that recites how the film was obtained is noted, however, process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. The drug elution rate of the film recited in Claim 1 is also noted, but does not put the water-soluble film in condition for allowance since products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The main base material, griseofulvin and sorbitol of the Yamamura et al patent anticipate the edible polymer, griseofulvin and sorbitol of instant Claim 1.

Claim Rejections - 35 USC § 103

8. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamura et al (US Patent No. 5,914,118).

Applicants claim a water soluble film preparation for oral administration comprising a drug, an edible polymer and a monosaccharide or an oligosaccharide, wherein the film is obtained by spreading and drying and has a drug elution rate of more than about 50% per 10 minutes and the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer in which the compound is at least one of nilvadipine, phenytoin or griseofulvin, and the monosaccharide or oligosaccharide is sorbitol or reducing maltose starch syrup. Additional limitations in the dependent claims include specific amount of the drug, edible polymer and monosaccharide or oligosaccharide in the film preparation; and specific type of edible polymer disclosed in the film preparation.

The Yamamura et al patent discloses a multi-layered film preparation for pain-killing and protecting an affected part of mucous membrane in the oral cavity, which comprises a water-soluble high molecular weight substance to be employed as a main base material. The Yamamura et al patent discloses that the main base material may be selected as hydroxypropylcellulose, hydroxypropylmethylcellulose and methylcellulose (for example), which anticipate the edible polymer of instant Claim 1. Yamamura et al discloses that the preparation may also include a drug and a plasticizer wherein the drug may be selected as griseofulvin (see column 3, line 66) and the plasticizer may be selected as sorbitol (see column 4, line 21). The limitation in Claim 1 that recites how the film was obtained is noted, however, process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. The drug elution rate of the film recited in Claim 1 is also noted, but is not seen to be a patentable limitation to obviate the art of record since products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir.

1990). See MPEP 2112.01. The instant claims differ from the Yamamura et al patent by claiming specific amounts of drug, edible polymer and monosaccharide or oligosaccharide. Applicants are reminded that the Office is in no position to determine experimentally whether or not, in an invention such as that at issue, the subject matter is the same as that of the reference. Accordingly, in such instances, this shifts the burden to the Applicants who have the resources to make such a determination and is in a better position to determine experimentally the differences between the invention as claimed and that of the art. *In re Pye*, 355 F2d 641, 148 USPQ 426 (CCPA 1966). In view of the fact that the instant claims and the Yamamura et al patent set forth analogous components in the film preparations and both film preparations are orally administered, it would have been obvious to one of ordinary skill in the art at the time of applicants invention to employ a water-soluble film preparation having the Yamamura et al patent before him in view of the closely related structures of the components of the film preparation and the resulting expectation of similar therapeutic properties.

Allowable Subject Matter

9. Claim 10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or fairly suggest a water soluble film preparation that comprises nilvadipine, a reducing maltose starch syrup, and one or more of poly(vinylpyrrolidone) and hydropropyl cellulose .

Summary

11. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

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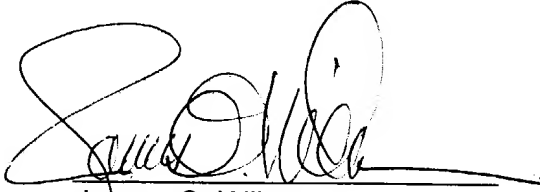
12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E.White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600